UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KAREN L., by her mother JANE L., and GRISEL HERNANDEZ, et al. *Plaintiffs,*	)	
	)	CIVIL ACTION NO. 3:99 CV 2244 (CFD)
v.	)	
HEALTH NET of the NORTHEAST, and PATRICIA WILSON-COKER, in her official capacity *Defendants.*	)	

RULING ON PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Pending is the plaintiffs' motion for a preliminary injunction [Doc. # 459]. The plaintiffs allege that the defendants did not comply with federal Medicaid statutes and regulations and the due process requirements of the Fourteenth Amendment of the United States Constitution when the composition of a preferred drug formulary was changed on October 1, 2002. Specifically, the plaintiffs allege that the notices provided by the defendant Health Net of the Northeast ("Health Net") regarding the changes to its formulary were deficient.

The defendant Patricia Wilson-Coker is the Commissioner of the Connecticut Department of Social Services ("DSS"). DSS is responsible for the administration of Medicaid in Connecticut. DSS contracts with managed care organizations ("MCOs") to provide medical services to Medicaid

recipients in Connecticut. The defendant Health Net is one of the four MCOs delivering services to approximately 300,000 Connecticut Medicaid recipients enrolled in managed care. Health Net has about 110,000 members. The class-action plaintiffs are Medicaid recipients who receive their services through Health Net.

The plaintiffs seek a preliminary injunction which would 1) prohibit the defendants from terminating any prescription drug benefit which was being provided to a Health Net Medicaid member prior to the formulary changes on October 1, 2002, without giving proper notice and 2) prohibit the defendants from rejecting claims made at pharmacies by Health Net Medicaid members for any drug that was being provided to the member and was removed from the formulary on October 1, 2002 without providing proper notice. For the following reasons, the motion is DENIED.

FINDINGS OF FACT

Based on the evidence presented at the hearing on the Motion for Preliminary Injunction, the Court makes the following Findings of Fact.

A. Overview of Connecticut Medicaid Managed Care Program

The Medicaid program was created in 1965 to provide federal financial assistance to states that incur the cost of medical care for low-income individuals. A state electing to participate in Medicaid must submit a plan to the U.S. Secretary of Health and Human Services ("Secretary") describing its medical assistance program. Upon approval of the plan submitted by the state, the Secretary allocates

federal grants to subsidize the state administered program. Among the health services states provide under Medicaid are prescription drug benefits.

In 1995, the Department of Health and Human Services's Centers for Medicare and Medicaid Services ("CMS") granted a waiver to DSS which permitted it to move most of its Medicaid recipients from the traditional fee-for-services program, which was administered directly by DSS, to managed care organizations. DSS entered into purchase of service contracts with the MCOs.

In 2000, when the waiver was scheduled to expire, CMS reviewed and reauthorized Connecticut's managed care system. In 2002, CMS promulgated a final rule creating a regulatory scheme to address the obligations of states that use managed care programs to provide Medicaid benefits. See Managed Care, 67 Fed. Reg. 40989, et seq. (June 14, 2002) (to be codified at 42 C.F.R. 438).

As noted above, in using the managed care system, DSS contracts with four different MCOs, including the defendant Health Net. In its contracts with the MCOs, DSS imposes on the MCOs the notice requirements and other obligations required by federal Medicaid law as well as additional contractual duties. DSS's contract with Health Net incorporates these requirements.

B. Managed Care and the Pharmacy Benefit

As part of its health care benefits, the Connecticut Medicaid program pays for all medically necessary and appropriate prescription drugs for its participants. Section 3.15 of DSS's contract with Health Net sets forth prescription drug requirements for Health Net to follow. Section 3.15 requires Health Net, among other things, to maintain a comprehensive network of pharmacies, to establish protocols to fulfill any urgent medication needs of Medicaid recipients, and to require its network of pharmacies to offer medically necessary goods and services to Medicaid recipients.

Section 3.15 of DSS's contract also permits the use of a "preferred drug list," commonly referred to as a prescription drug formulary. Health Net, as well as two of the other MCOs, use a formulary.

Under the Health Net formulary, there are essentially two categories of prescription drugs. First, there are drugs for which no prior authorization from Health Net is required, *i.e*., formulary drugs. If a recipient is prescribed one of these drugs by a physician, he or she can obtain it at the pharmacy without any review by Health Net for medical necessity or appropriateness. Second, there are drugs for which prior authorization from Health Net is required, *i.e.*, non-formulary drugs.[1]

With respect to the formulary drugs, DSS requires that Health Net and the other MCOs include a reasonable selection of drugs in all therapeutic classes. Section 3.15(b) of the contract expressly requires that the formulary provide "a reasonable selection of drugs which do not require prior authorization for each specific therapeutic drug class." DSS periodically reviews the formulary to ensure that such a selection exists. Accordingly, the formulary provides physicians with a list of prescription medications that are available to their patients without authorization and which includes several alternatives in each therapeutic class.

Medicaid recipients may obtain non-formulary drugs (other than a small number that are outside the Medicaid program) if they have a prescription by a physician and authorization from Health Net. The authorization process may be initiated either by a request by the prescribing doctor, which would

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[1] Some of the drugs for which prior authorization is required are listed on the formulary as requiring prior authorization; others are not listed on the formulary. A recipient can obtain a drug that is not listed on the formulary by way of authorization. For purposes of the preliminary injunction motion, the distinction between drugs on the formulary for which prior authorization is required and those not on the formulary for which prior authorization is required is not relevant. For the sake of simplicity, the Court's references to "formulary drugs" are to drugs for which no prior authorization is required; the Court's references to "non-formulary drugs" are to drugs for which prior authorization is required.

result in a prior authorization review or by presentation of a prescription for a non-formulary drug to the pharmacy, which would result in a standard authorization review if prior authorization had not been sought. Health Net reviews the authorization requests to determine whether the prescribed drug is medically necessary and appropriate. If Health Net finds that the drug is medically necessary and appropriate, then the request is approved, and Health Net will pay for the drug when the recipient goes to the pharmacy to fill the prescription. If Health Net finds that the drug is not medically necessary or appropriate, then Health Net sends a "Notice of Action" ("NOA") to the recipient that informs the recipient of Health Net's action and of the right to appeal.

C. Health Net's October 2002 Formulary Changes

Effective October 3, 2002, Health Net made two principal changes to its formulary. First, it provided that 105 of the formulary drugs would henceforth require prior authorization. Second, it applied the formulary to children in the responsibility of the Connecticut Department of Children and Families ("DCF"), who previously had been exempt from the formulary. In addition, Health Net changed what had been previously described as a "one-time temporary supply" system to an "urgent or emergent" system.[2] Health Net also added quantity limits, *i.e.*, a limit on the amount of a drug that

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[2]Under the "urgent or emergent system," a Medicaid recipient can receive a one-time supply of a non-formulary drug if the recipient's doctor certifies that the need for the drug is "urgent or emergent." If the doctor so indicates, the prescription is filled and Health Net undergoes a review to determine if the drug is "medically necessary and appropriate." If the drug is medically necessary and appropriate, the recipient may continue to receive the drug. If the doctor does not believe the need for the drug is urgent or emergent, the doctor may instead prescribe one of the formulary alternatives, negating the need for a review of medical necessity and appropriateness.

Under this system, when a Medicaid recipient presents a prescription for a non-formulary drug at the pharmacy, the pharmacist is instructed to contact the recipient's physician and inquire whether the need for the drug is "urgent or emergent." If the physician is unavailable, the pharmacist is directed to fill the prescription as if it had been certified as urgent/emergent, which also triggers a review by Health

(continued...)

could be prescribed at any one time without prior authorization, to 32 of the formulary drugs.

DSS's policy with respect to formulary changes is to review the altered formulary in advance to confirm that it contains sufficient drugs in each therapeutic class to satisfy section 3.15(b) of the contract. With respect to formulary changes that affect maintenance drugs, *i.e.*, drugs used to treat chronic or long-term conditions, DSS imposes additional requirements on Health Net. Health Net is required by the contract to give advance notice of formulary changes to members who are taking maintenance drugs that will be affected by the changes. Health Net is also required by the contract to provide "aid pending" appeal if prior authorization for a new prescription of a maintenance drug is denied.[3]

Starting in August 2002, Health Net and DSS discussed both the substance of the changes to the formulary and how Health Net planned to implement the changes. Among other things, they discussed the content of the letters to be sent to members who would be affected by the changes. DSS

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[2](...continued)
Net for medical necessity and appropriateness.

While this system was new to Health Net, it is similar to systems utilized by two other Connecticut HMOs–Anthem Blue Cross and Blue Shield of Connecticut and Community Health Network of Connecticut.

[3]The parties differ in their views of whether advance notice of formulary changes and "aid pending" are also required by federal regulations. With regard to formulary changes: the plaintiffs believe that a change in the formulary requires an NOA for those members receiving a drug that is removed from the formulary or requires prior authorization. The defendants, however, assert the removal of a drug from the formulary is not a "denial" that requires notice, since Health Net will still pay for the drug if it is medically necessary and appropriate. Rather, they assert that an NOA is not required until Health Net has completed a medical necessity review and determined that it will not pay for the drug.

As to "aid pending," the plaintiffs maintain that removal from the formulary of a drug that a member was receiving is a "termination" of a benefit, which triggers the aid pending right under the Medicaid regulations. The defendants claim that, even for so-called "maintenance" drugs (i.e., drugs that members have been receiving over a period of time), the refusal to fill a new prescription is a "denial" of a new benefit, not a "termination" of an ongoing benefit, and therefore aid pending is not required under the regulations.

approved Health Net's formulary changes and the informational letters to be sent to members who would be affected. In addition, DSS reviewed informational letters about the formulary changes that Health Net planned to send to doctors and pharmacists. DSS requested changes to these letters to improve the descriptions of prior authorization and the "urgent or emergent" systems, and Health Net agreed to DSS's suggested changes.

Starting in early September, Health Net sent letters providing notice of the formulary changes to members who would be affected by the changes on October 1. The letters described the changes to the formulary, the prior authorization opportunity, the right to appeal any denials of authorization, and of the opportunity to receive aid pending.

Health Net sent the first group of letters to members who had filled prescriptions in July and August 2002 for drugs that would be affected by the formulary changes. A second group of letters followed in October; these were sent to members who had filled prescriptions in the first two weeks of September for drugs affected by the formulary changes. The third group of letters went out in October and into early November, to members who had filled prescriptions for affected drugs in late September. In all, Health Net sent over 8,000 informational letters to affected recipients.

Health Net also sent faxes and subsequent informational letters to pharmacists and doctors. These letters described the changes to the formulary and various procedures, including the "urgent/emergent" system. The letters to the pharmacists emphasized the importance of not letting a recipient leave the pharmacy without a prescribed drug unless there was a confirmation by the prescribing physician that the drug was not needed on an urgent or emergent basis.

The formulary changes have now been implemented, with no apparent reduction in access to needed medications.

D. Problems Implementing the October 2002 Formulary Changes

1. "Urgent or Emergent System"

The plaintiffs have pointed out several instances in which pharmacists did not follow the procedures of the "urgent or emergent" system after the formulary changes were implemented. In early October a number of Health Net pharmacists were not properly adhering to the urgent or emergent override system. Health Net then responded by implementing a back-up "safety net" system. Under this transitional back-up system, all prescriptions for non-formulary maintenance medications were filled during October, and then Health Net initiated the standard authorization process for each medication.

2. Incorrect Notice of Action Template

In addition, in at least 92 instances between October 1 and December 15, Health Net used an incorrect NOA template to communicate that requests for prior authorization had been denied. The incorrect NOA did not include an explanation that the recipient would receive "aid pending" appeal if an appeal was taken in a timely manner. On discovering this error, Health Net issued revised NOAs to each recipient.

3. Notices to DCF Children

Some of the 3,600 DCF children enrolled in Health Net's plan were receiving maintenance drugs that were affected by the formulary changes. Some of the affected children and their adult care givers did not receive the informational letter providing advance notice about the formulary changes. According to Health Net, this oversight was the result of a "computer coding error." After the problem was brought to Health Net's attention, it first identified the DCF children who might have ongoing problems in getting access to maintenance medications. It then contacted the physicians for these 171 children in order to resolve any problems that might still exist.

When Health Net sends a Notice of Action to a DCF child (or to the child's foster or adoptive parents), *e.g.*, because the medical necessity review finds that a non-formulary drug is not medically necessary, Health Net also sends a copy of the Notice to DCF. The DCF copy serves as a backup and is not intended to be the principal notice, which is sent to the DCF child's foster or adoptive parents; the parents, on behalf of the child, have the right to appeal adverse decisions. DCF enters the notices into a database, and distributes them to DCF employees once a month.

While the record indicates that effective notice of changes to DCF children was a problem just after the formulary changes became effective for the reasons noted above, the record also indicates that those problems have been corrected through the defendants' coordination with DCF.

4. The Cases of the Individual Witnesses

Three witnesses testified at the injunction hearing regarding their individual experiences. One of them, Marisol Arroyo-Pratts, testified that, after receiving advance notice that Celebrex was to become a non-formulary drug, she obtained prior authorization to continue using Celebrex. She also testified that she was unable to fill a prescription for Zyrtec in late October–a drug for which she had not received advance notice. Arroyo-Pratts did not contact her doctor after she was unable to fill her prescription for Zyrtec, but used her own supply of a different asthma medication during the month of November. However, she was able to fill her prescription for Zyrtec at the end of November, and continues to receive the drug, with prior authorization.

Gloria Barton and John Magnano also testified at the hearing. Both witnesses testified that they did not receive advance notice of formulary changes which affected the children in their care, but both also testified that the children continue to receive their prescribed medications, and have received the necessary prior authorizations from Health Net and refunds for their out-of-pocket expenditures in

purchasing medications prior to Health Net authorization..

The record shows that no Medicaid recipient is currently not receiving necessary or appropriate medications, and no recipients or group of recipients faces the threat of losing access to necessary or appropriate medications. There are also no ongoing problems with the Health Net prior authorization system that would threaten to deprive Medicaid recipients of such access, or of any other policies or practices that would threaten to prevent recipients from receiving any notices to which they might be entitled. Although Health Net made some mistakes in implementing the formulary changes–especially concerning the DCF children–Health Net has both acted to remedy problems that stemmed from the implementation of the new system and has created new systems to avoid future problems.

CONCLUSIONS OF LAW

I. Standard for Preliminary Injunctive Relief

The Second Circuit has cautioned that preliminary injunctive relief relief "is an extraordinary and drastic remedy which should not be routinely granted." Buffalo Forge Co. v. Ampco-Pittsburgh Corp., 638 F.2d 568, 569 (2d Cir.1981) (internal quotation marks omitted). Ordinarily, entry of a preliminary injunction is appropriate where the party seeking the injunction establishes: (a) the injunction is necessary to prevent irreparable harm, and (b) either (i) likelihood of success on the merits, or (ii) sufficiently serious questions going to the merits of the claim as to make it fair ground for litigation, and a balance of the hardships tips decidedly in favor of the movant. See, e.g., Able v. United States, 44 F.3d 128, 130 (2d Cir.1995). Thus, the first part of the standard–irreparable harm–must always be met, but the party seeking an injunction may satisfy the second prong by establishing *either* a likelihood of success or sufficiently serious questions going to the merits and a balance of hardships in its favor. However, "[w]hen a plaintiff seeks an injunction staying governmental action 'taken in the public interest

pursuant to a statutory or regulatory scheme,' . . . an injunction will issue only if the plaintiff can show irreparable injury and meet 'the more rigorous likelihood-of-success standard.'" Fair Housing in Huntington Committee, Inc. v. Town of Huntington, 316 F.3d 357 (2d Cir. 2003) (quoting Bery v. City of New York, 97 F.3d 689, 694 (2d Cir. 1996). Thus, because this case involves "governmental action taken in the public interest pursuant to a statutory or regulatory scheme," the plaintiffs must establish irreparable harm and a likelihood of success on the merits in order for an injunction to enter.

II. There is No Threat of Irreparable or Imminent Harm

With regard to procedural violations, including constitutional due process claims, a plaintiff must independently establish irreparable harm in order to support preliminary relief. See Jayaraj v. Scappini, 66 F.3d 36, 40 (2d Cir. 1995). In Jayaraj, the court vacated a preliminary injunction based in part on alleged violations of the Due Process Clause for failure to show irreparable harm, emphasizing that "law of this Circuit requires the party moving for a preliminary injunction to show that it will suffer imminent irreparable harm." Id. at 40; see also, e.g., Air Transport International Ltd. Liability Co. v. Aerolease Financial Group, Inc., 993 F. Supp. 118 (D. Conn. 1998).

The evidence demonstrates that the October, 2002 changes in Health Net's formulary did not result in any system-wide reductions in the filling of prescriptions for Medicaid members served by Health Net. There is no evidence that any Medicaid recipient is being denied access to needed medications or that any recipients are threatened with such a denial. There is no evidence of any threatened or imminent harm. Plaintiffs' evidence showed some problems in the issuance by Health Net of informational letters describing the October formulary changes, of some subsequent NOAs, and efforts to notify DCF children of the changes. However, Health Net has shown that these problems have been corrected. Moreover, the evidence shows that no irreparable harm to Medicaid recipients

has occurred and that the formulary system is not likely to repeat the problems which occurred in the fall of 2002. There is no evidence of any ongoing harm or that an injunction is needed to protect Medicaid recipients.

III. There is No Likelihood of Success on the Merits

The plaintiffs' failure to demonstrate irreparable harm is alone sufficient to deny the request for a preliminary injunction. See Jayaraj, 66 F.3d at 38-39 ("Because we hold that [plaintiff] failed to establish that he would suffer irreparable harm in the absence of an injunction, there is no need to reach the second portion of the preliminary injunction analysis."). However, even if the plaintiffs had shown that in the absence of an injunction they would suffer irreparable harm, they have failed to satisfy the second portion of the preliminary injunction test as they have not demonstrated a likelihood of success on the merits.

The plaintiffs concede that the formulary changes are lawful. The plaintiffs' challenge is limited to the letters describing the October 2002 formulary changes and to the notices regarding the ability of Medicaid recipients to continue to receive a medication pending an appeal of a decision by Health Net denying prior authorization.

Health Net sent informational letters in advance of the October 1 formulary changes to the recipients potentially affected by the changes, as well as notices to pharmacies and physicians. The letters did not purport to deny or terminate any services, but were for informational purposes. The Federal Medicaid regulations require MCOs to provide aid pending appeal only in certain circumstances. When an MCO terminates, suspends, or reduces previously authorized services, the MCO must (with some exceptions) mail an NOA ten days before the effective date of the action, see 42 C.F.R. § 438.404(c)(1), 42 C.F.R. § 431.211, and a member is entitled to "aid pending," that is,

continuation of benefits during the pendency of any appeal of the action. See 42 C.F.R. § 438.420. As noted above, the defendants argue that the failure to fill a new prescription for a maintenance drug is not a termination, giving rise to aid pending rights, but a denial, which does not require aid pending. The plaintiffs claim that if a "fill" of a prescription for a maintenance drug is refused, that action is a termination and gives rise to aid pending rights. However, whatever the requirements of Medicaid regulations, as a matter of State policy, DSS placed requirements in its MCO contracts that provide for "aid pending" after denials of requests for new prescriptions of maintenance medications included within a formulary change. Additionally, as a matter of Health Net policy, Health Net uses the termination NOA template when it concludes that a new request for a schedule II drug, which a member had been receiving continuously in the past, is not medically necessary and appropriate. While this Court agrees with the plaintiffs that some of the improper NOAs did not contain the aid pending language required under the contract, the record indicates that Health Net has corrected this situation, and, regardless of whether the Medicaid regulations require aid pending in this situation, the plaintiffs have not carried their burden of demonstrating that there is ongoing or imminent harm stemming from class members being denied access to their aid pending rights.

The defendants argue that incidental or inadvertent gaps do not violate due process or the federal Medicaid laws, which require only substantial compliance with their terms. The defendants cite several cases in which the administration of other federal assistance programs was held to a "substantial compliance" standard. See Moore v. Perales, 692 F.Supp. 137, 145 (E.D.N.Y.1988) (holding that "only substantial compliance is required" in administering the Food Stamp Act and that "[o]nly a failure to comply substantially with the provisions will incur liability to private parties."); Blessing v. Freestone, 520 U.S. 329, 343 (1997) (holding that substantial compliance with the terms of the federal AFDC

program requires examination of "the aggregate services provided by the State, not whether the needs of any particular person have been satisfied"); Richardson v. Wright, 405 U.S. 208, 209 (1970) ("In the context of a comprehensive, complex administrative program the administrative process must have a reasonable opportunity to evolve procedures to meet needs as they arise"); Shands v. Tull, 602 F.2d 1156, 1160-61 (3d Cir.1979) (finding that the statutory provisions concerning AFDC "show an implied intent to hold the states to a standard of substantial compliance and this to make some allowance for the difficulties of administering an extensive bureaucracy."); Roberta G. v. Perales, No. 90 CIV 3485, 1992 WL 320469, at *5 (S.D.N.Y. Oct. 23, 1992) (stating that "I find the acceptance of less than 100% compliance reasonable and not unfair to class members").

As with the AFDC statutory provisions at issue in Shands, federal Medicaid law contemplates something less than total and absolute compliance. See 42 U.S.C. § 1396c (authorizing the Secretary to cease payments to the state if, inter alia, "there is a failure to comply substantially with any such provision [of section 1396a of Title 42]"). The plaintiffs have not shown that the defendants have failed to substantially comply with the standards governing the Medicaid program. The evidence demonstrates that defendants are and have been in substantial compliance with federal law and the regulations governing Connecticut's Medicaid program. Plaintiffs have failed to prove the existence of substantial noncompliance on a systemic level. The problems that occurred in implementing the October 2002 formulary revisions were not the result of a system that did not substantially comply with the Medicaid regulations, but rather were the result of Health Net's "urgent or emergent" system not being followed by pharmacists and doctors and of Health Net's own errors in sending out NOAs. The evidence indicates that these problems, which were incidental to implementing the formulary changes, were corrected and in a fashion to avoid irreparable harm. See (Defs.' Ex. 101 at 58:8-18)

(Magistrate Judge Garfinkel distinguishing between intentional policy decisions from occasional failure to comply with policy for purposes of substantial compliance.) Plaintiffs have not established a class-wide violation of constitutional, statutory or regulatory law; they have only shown isolated problems that were immediately remedied upon discovery.[4]

IV. Conclusion

For the preceding reasons, the plaintiffs' motion for a preliminary injunction [Doc. # 459] is denied.[5]

SO ORDERED this ___ day of June, 2003, at Hartford, Connecticut.

CHRISTOPHER F. DRONEY
UNITED STATES DISTRICT JUDGE

[4]The Court has also considered the plaintiffs' argument that the issues involved in this case are "identical" to the due process issues in Rabin v. Wilson-Coker, No. 3:03cv555RNC, 2003 WL 21277346 (D. Conn. May 29, 2003), a case in which the Court issued a temporary restraining order, but then denied a motion for preliminary injunction. See Id. However, the facts here are not analogous to the facts in Rabin. In Rabin, the challenged notices involved a termination of Medicaid eligibility. This case, in contrast, does not involve a termination of Medicaid eligibility. Moreover, as noted above, there was insufficient evidence here that any plaintiff is currently being, or is likely to be, denied access to medically necessary and appropriate medications.

[5]Also pending is a Motion to Intervene filed by the Child Advocate on December 4, 2002. While the Court has not yet ruled on the Child Advocate's motion, it did consider the arguments made by the Child Advocate in rendering this decision.